Guidelines on the Nonconformity Grading and Exchange Form
MDSAP AU G0019.4.002

Purpose

This guidance document explains the features of the Excel Form MDSAP AU F0019.2 - *MDSAP Nonconformity Grading and Exchange Form*, and clarifies how to use it.

Preamble

The form MDSAP AU F0019.2 - MDSAP Nonconformity Grading and Exchange Form – must be filled out and provided to the Regulatory Authorities as part of every audit report package (One record per audit report). If there are more than 30 nonconformities identified during an audit, the audit team must use more than one file, where the file names would be differentiated by the version number.

The form should also be used to provide the Regulatory Authorities with an early warning, as described in document MDSAP AU P0027 – Post Audit Activities and Timeline Policy.

Compatibility

The form was developed using Microsoft EXCEL 2010 but was saved in a format that should be compatible with earlier versions of Microsoft EXCEL. While some compatibility tests were successfully performed, some functions/features in the form may not be fully compatible with all systems. Please report any difficulty using this form by email to MDSAP@fda.hhs.gov.

Excel Workbook Protection

The form displays cells containing formulas in orange. Most of the orange cells are protected to prevent the loss of functions. Some columns are not protected though, as clarified in section *Tab 2. Nonconformities* below. Changing these cells may affect their functioning.

Content of the Form

Tab 1. Audit Information

This worksheet records basic traceability information regarding the audit:

- Audited Facility,
- Audited Facility's DUNS#,
- Audit Start Date, and
- Audit End Date.

It also requires specifying the record version number. The version number can be used for keeping track of several versions of the record, and saving multiple "partial" records. Examples of "partial" records include:

- When the total number of nonconformities exceed the worksheet cap of 30 nonconformities, or
- When each audit team member fills in separate nonconformity forms to be eventually merged.

All these fields must be filled in. The information enables the form to generate:

- The Audit Report Reference, and
- Record File name.

Saving the file

The button Save Record As ensures that the record is saved using the appropriate file name format according MDSAP QMS P0015 – *Naming Convention of MDSAP Electronic Records*. The record should be saved using this button each time any of the information is updated.

Nonconformity Summary Table

This worksheet also displays some summary information on the nonconformities:

- Number of nonconformity of each grade
- Total number of nonconformities
- Number of closed nonconformities.

Printing the Report

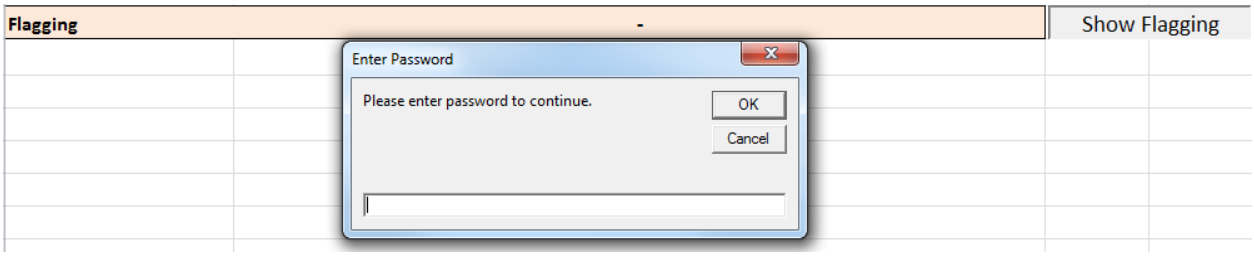
The button Print Record prints the entire workbook (both tabs) in a printer-friendly format to the user's default printer. To print on a different printer, the user must change the default printer to the appropriate printer before clicking on the *Print Record* button. (In Windows 7 or earlier version, click the Start button in the bottom left corner, select *Devices and Printers* in the Start Menu, right-click on the appropriate printer and select *Set as default printer*.)

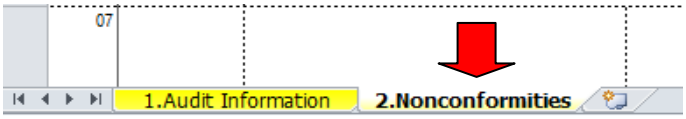
The printer-friendly view hides the ISO 13485 and regulatory *Task-related clauses* columns. Note: To ensure the consistency of the printed information, the file needs to be saved using the Save Record As button before printing (the header includes the file name, which must be consistent with cell B9 of tab *1.Audit Information*.)

Report Flagging

This worksheet eventually enables Regulatory Authorities receiving the report to reveal the flagging status of the report, using the Show Flagging button.

The flagging facilitates triaging incoming reports. The flagging is password protected and is not accessible to the Auditing Organizations.





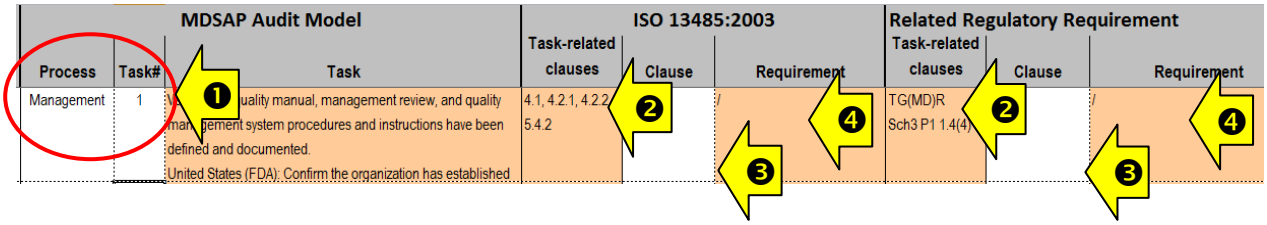
Tab 2. Nonconformities

NC Description

For each identified non conformity, the auditor must specify the following:

- NC#: unique identifier of the nonconformity
- NC Statement: statement of nonconformity
- Evidence: supporting evidence of the nonconformity
- MDSAP Audit Model Process: select the process in the drop-down list attached to the cell
- MDSAP Audit Model Task#: specify the task # within the selected MDSAP Audit Model Process. The text of the task will appear in the next column
- ISO 13485 Clause: a nonconformity must refer to a unique clause. Select the clause in the drop-down list. Once selected, the ISO 13485 requirement appears in the next column.
- Regulatory Requirement Clause: As applicable, the nonconformity must refer to a unique country-specific clause. Once selected, the regulatory requirement appears in the next column.

When the MDSAP Audit Model *Process* and *Task#* are specified❶, the ISO 13485 and regulatory "task-related clauses" columns❷ display clauses specified in the document MDSAP AU P0002 – Audit Model to help the auditor identify the clauses likely relevant to the nonconformity. Select the clause from drop-down lists in the ISO 13485 or regulatory clause columns❸. Once a clause is selected, the corresponding requirement appears in the next column❹.



If a nonconformity does not relate to a country-specific regulatory requirement, select "NA" in the drop-down list.

A nonconformity may relate to only part of a specified ISO 13485 and/or regulatory clause. The auditors should edit the clause to only keep the part that is relevant to the nonconformity.
To edit the text of the clause, the auditor must:

1. Select the cell,
2. Copy the cell (Ctrl+C or right-click on the cell and select "Copy" in the menu)
3. Stay in the same cell, right-click and select *Paste option: Values* (123) or *Paste Special: Values*.

Note: After pasting the *requirement* cell, it does no longer include a formula. Selecting a different clause does no longer update the content of the *requirement* cell.

Nonconformity Grading

For each identified non conformity, the auditor must also grade the nonconformity based on the grading attribute:

- For *Baseline per ISO 13485 clause*, the form automatically determines the value (1 or 3) when the ISO 13485 clause is selected.
- For *Repeat NC*, *Lack or required document* and *Released nonconforming products*, enter 0 if not applicable or 1 if applicable (these cells should not be left blank). See GHTF SG3 document N19 for clarification of these grading attributes.

Nonconformity previously recognized by the manufacturer

Select Y(Yes) if the nonconformity was previously identified, recorded and is being appropriated handled by the manufacturer as specified in MDSAP AU P0019 – section 2.3.3 – *Audit findings*. Select N(No) in any other case.

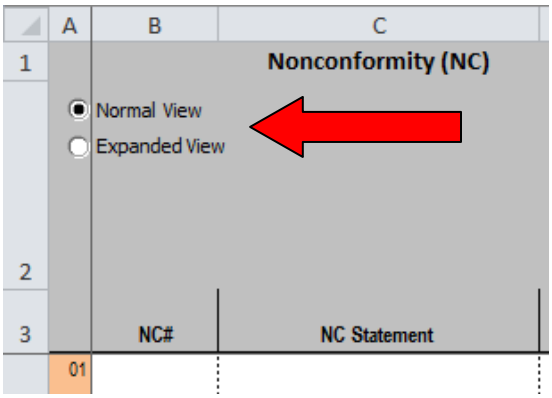
Nonconformity Status

When the MDSAP NC Grading and Exchange Form is provided with the audit report, the AO must also select in the drop-down lists the status of the *Correction Plan*, *Correction*, *Corrective Action Plan*, *Corrective Action* and of the nonconformity (*Closed?*).

Reminder: A nonconformity is closed only when the AO has verified the appropriateness of the action plan and the effectiveness of the implemented actions.

Pre-set Views

The tab *2.Nonconformities* has 2 pre-set views that are activated by a radio-button in the upper left corner of the worksheet

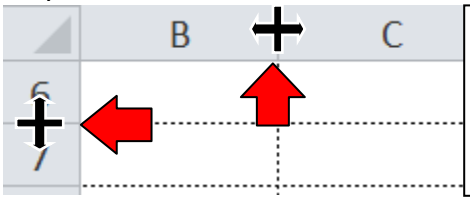


The *Normal View* has narrower columns and the rows' height adjusts to fit the content of the cells;

The Expanded View has wider columns containing long texts, but a fixed height.

By default, the file is set on the *Expanded View*. This view is more convenient to populate the table, using the drop-down lists. Once the table is complete, the *Nomal View* presents the entire set of information.

In both the *Normal View* and *Expanded View*, the user can manually change the columns' width and the rows' height, either by dragging the lines as shown on the picture below, or or by right-clicking the column- or row-header and selecting "Column Width…" or "Row Height…" in the drop-down menu.

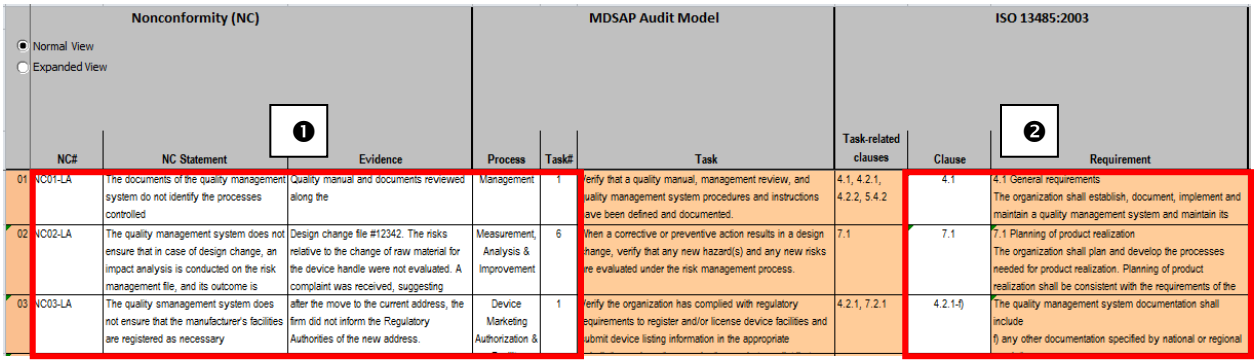


To shrink or expand a column of a row, place the cursor on the separating line on the right of the column or below the row, as shown by the arrows on the picture, and left-click and move the cursor to drag the line.

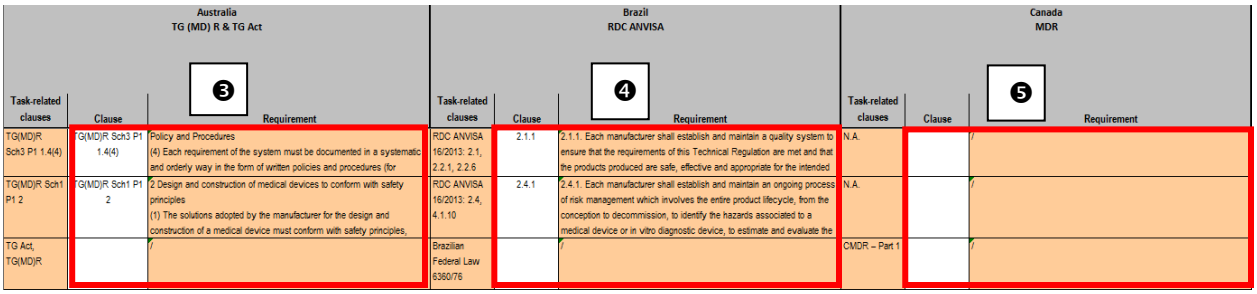
Merging nonconformity information from multiple files

If each member of an audit team writes their nonconformities on a separate file, it is necessary to merge the information on all nonconformities into a single file. Because some cells are protected in the workbook, it is not possible to copy the entire set of information from one file and paste it into the other. The protected cells are columns A, G, H, K, N, Q, T, W and AA. The suggested process is to copy and paste the information by bloc, for all nonconformities together:

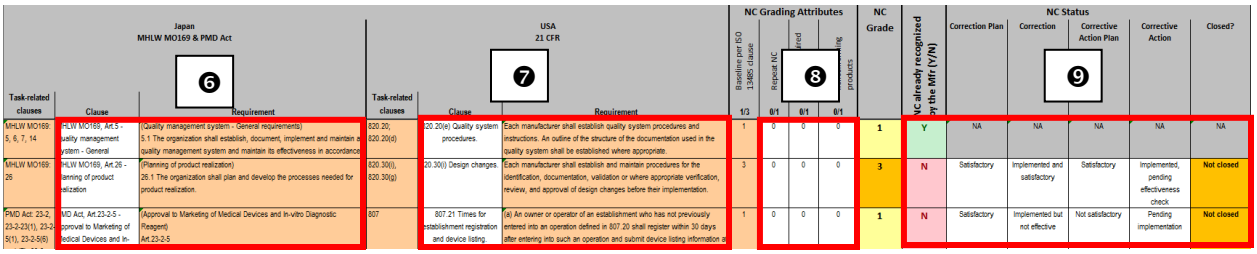
- Columns B to G (NC#, NC Statement, Evidence, Process, Task# and Task) ❶
- Columns I and J (ISO 13485 Clause and Requirement) ❷
- Columns L and M (Australian Regulation Clause and Requirement) ❸
- Columns O and P (Brazilian Regulation Clause and Requirement) ❹
- Columns R and S (Canadian Regulation Clause and Requirement) ❺
- Columns U and V (Japanese Regulation Clause and Requirement) ❻
- Columns X and Y (US Regulation Clause and Requirement) ❼
- Columns AA to AC (Repeat NC, Lack or Required Document, and Released Nonconforming Products) ❽
- Columns AE to AJ (Correction Plan, Correction, Corrective Action Plan, Corrective Action, and Closed?) ❾



Nonconformity (NC)			MDSAP Audit Model			ISO 13485:2003		
NC#	NC Statement ❶	Evidence	Process	Task#	Task	Task-related clauses	Clause ❷	Requirement
01	NC01-LA	The documents of the quality management system do not identify the processes controlled	Quality manual and documents reviewed along the	Management	1	Verify that a quality manual, management review, and quality management system procedures and instructions have been defined and documented.	4.1, 4.2.1, 4.2.2, 5.4.2	4.1	4.1 General requirements The organization shall establish, document, implement and maintain a quality management system and maintain its
02	NC02-LA	The quality management system does not ensure that in case of design change, an impact analysis is conducted on the risk management file, and its outcome is	Design change file #12342. The risks relative to the change of raw material for the device handle were not evaluated. A complaint was received, suggesting	Measurement, Analysis & Improvement	6	When a corrective or preventive action results in a design change, verify that any new hazard(s) and any new risks are evaluated under the risk management process.	7.1	7.1	7.1 Planning of product realization The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the
03	NC03-LA	The quality smanagement system does not ensure that the manufacturer's facilities are registered as necessary	after the move to the current address, the firm did not inform the Regulatory Authorities of the new address.	Device Marketing Authorization &	1	Verify the organization has complied with regulatory requirements to register and/or license device facilities and submit device listing information in the appropriate	4.2.1, 7.2.1	4.2.1-f)	The quality management system documentation shall include f) any other documentation specified by national or regional



Australia TG (MD) R & TG Act			Brazil RDC ANVISA			Canada MDR		
Task-related clauses	Clause	Requirement ❸	Task-related clauses	Clause	Requirement ❹	Task-related clauses	Clause	Requirement ❺
TG(MD)R Sch3 P1 1.4(4)	TG(MD)R Sch3 P1 1.4(4)	Policy and Procedures (4) Each requirement of the system must be documented in a systematic and orderly way in the form of written policies and procedures (for	RDC ANVISA 16/2013: 2.1, 2.2.1, 2.2.6	2.1.1	2.1.1. Each manufacturer shall establish and maintain a quality system to ensure that the requirements of this Technical Regulation are met and that the products produced are safe, effective and appropriate for the intended	N.A.		/
TG(MD)R Sch1 P1 2	TG(MD)R Sch1 P1 2	Design and construction of medical devices to conform with safety principles (1) The solutions adopted by the manufacturer for the design and construction of a medical device must conform with safety principles,	RDC ANVISA 16/2013: 2.4, 4.1.10	2.4.1	2.4.1. Each manufacturer shall establish and maintain an ongoing process of risk management which involves the entire product lifecycle, from the conception to decommission, to identify the hazards associated to a medical device or in vitro diagnostic device, to estimate and evaluate the	N.A.		/
TG Act, TG(MD)R		/	Brazilian Federal Law 6360/76		/	CMDR – Part 1		/



Japan MHLW MO169 & PMD Act			USA 21 CFR			NC Grading Attributes				NC Grade	NC already recognized by the MAH (Y/N)	NC Status				
Task-related clauses	Clause	Requirement ❻	Task-related clauses	Clause	Requirement ❼	Baseline per ISO 13485 clause 1/3	Repeat NC 0/1	Required 0/1	Missing products 0/1 ❽			Correction Plan	Correction	Corrective Action Plan ❾	Corrective Action	Closed?
MHLW MO169: 5, 6, 7, 14	MHLW MO169, Art.5 - Quality management system - General	(Quality management system - General requirements) 5.1 The organization shall establish, document, implement and maintain a quality management system and maintain its effectiveness in accordance	820.20; 820.20(d)	820.20(e) Quality system procedures.	Each manufacturer shall establish quality system procedures and instructions. An outline of the structure of the documentation used in the quality system shall be established where appropriate.	1	0	0	0	1	Y	NA	NA	NA	NA	NA
MHLW MO169: 26	MHLW MO169, Art.26 - Planning of product realization	(Planning of product realization) 26.1 The organization shall plan and develop the processes needed for product realization.	820.30(i), 820.30(g)	820.30(i) Design changes	Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.	3	0	0	0	3	N	Satisfactory	Implemented and satisfactory	Satisfactory	Implemented, pending effectiveness check	Not closed
PMD Act: 23-2, 23-2-23(1), 23-2-5(1), 23-2-5(6)	MD Act, Art.23-2-5 - pproval to Marketing of edical Devices and In-	(Approval to Marketing of Medical Devices and In-vitro Diagnostic Reagent) Art.23-2-5	807	807.21 Times for establishment registration and device listing.	(a) An owner or operator of an establishment who has not previously entered into an operation defined in 807.20 shall register within 30 days after entering into such an operation and submit device listing information a	1	0	0	0	1	N	Satisfactory	Implemented but not effective	Not satisfactory	Pending implementation	Not closed

Revision history

Version No	Version Date	Description of Changes	Author/Project Manager
001	2013-08-09	Initial Release	Marc-Henri Winter, FDA
002	2015-10-09	Added paragraph on nonconformity previously recognized by the manufacturer Updated the paragraph on merging nonconformity information from multiple files, to reflect the changes of the form	Marc-Henri Winter, FDA